REMARKS

Claims 7, 10-12, 28-35, 37-40, 43, 46 and 54-59 remain pending in this application. No amendments have been made. Based on the following remarks, reconsideration and allowance of this application is respectfully requested.

I. Claims 7, 10, 11, 28, 30-33, 37-40, 43, 46, and 54-59 Are Patentable Over Samson, Geeham, Lundback and Ostroff

Independent claims 7, 28 and 43 and respective dependent claims 10, 11, 30-33, 37-40, 46, and 54-59 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,185,442 to Samson ("Samson") in view of U.S. Patent no. 5,295,481 to Geeham ("Geeham"), U.S. Patent No. 4,736,749 to Lundback ("Lundback") and U.S. Patent No. 7,149,575 to Ostroff *et al*. ("Ostroff"). Applicant respectfully traverses this rejection because no proper combination of Samson, Geeham, Lundback, and Ostroff discloses, teaches, or suggests the combination of elements required by these claims.

Independent claims 7, 28 and 43 are directed to surgical apparatuses that include a flexible suction device "having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue." The size and shape of the suction device is described in more detail in paragraph [0164] of U.S. Patent Application Publication No. 2005/0119648.

In contrast, Samson describes a device directed to applying a suction cup 10 to a head 11 of a fetus. The suction cup 10 taught by Samson is much too large to be secured to myocardial tissue. Despite this, the Office Action alleges (in lines 5-7 on p. 3) that the suction cup 10 taught by Samson has a flexible distal portion that includes a peripheral sealing surface 13 having a shape and a size for being removably securable to myocardial tissue. Applicant respectfully disagrees with this characterization of the device taught by Samson. The suction cup 10 taught by Samson is configured for being secured to a patient's skin (i.e., the scalp of a fetus) and for being evacuated so that the electrode 16 within the suction cup 10 makes contact with the patient's skin in order to obtain a signal at the skin surface. Thus, the electrode 16 must be of a sufficient size for obtaining a signal at the patient's skin surface and the suction cup 10 must be of a sufficient size for housing the electrode 16. Hence, the size of the peripheral sealing surface 13 of Samson's suction cup 10 is necessarily too large to be secured to myocardial tissue.

The other cited references do not cure this deficiency in Samson. Geeham describes a CPR assist device that includes a column member 16, handles 18a and 18b, and a suction cup member 20. As is well understood, a CPR device is not designed or configured for use as a suction device applied to myocardial tissue, and the Office Action has provided no extrinsic evidence to this effect. Consistent with this conclusion is that Geeham describes a device having defibrillation electrodes 32 located at the peripheral rim 30 of the suction cup member 20. During use, an aid giver grabs the handles 18a, 18b and administers cycles of compression and expansion by pressing down on the chest and pulling up away from the chest. The suction cup member 10 provides a transfer of force safely and noninjuriously to the patient, and the act of pulling the CPR assist device away from the patient's chest results in a suction action that draws the chest upwardly with the movement of the suction cup member. (Geeham, col. 4, lines 19-37). Thus, the device described by Geeham is sufficiently large to be forcefully manipulated by a person grabbing handles 18a, 18b.

Thus, Geeham fails to disclose, and is not related to, a flexible suction device having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue as recited in claims 7, 28, and 43. While Geeham may disclose a heart-related device, the structure and functionality of a CPR assist and defibrillation device described by Geeham are very different and not related to Applicant's claims, particularly considering that the CPR assist device does not include a suction device having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue. Thus, not only is Geeham deficient relative to these claim limitations, but Geeham also teaches away from devices having a shape and size for being removably securable to myocardial tissue given the particular structure and manner in which the device of Geeham is utilized.

Lundback is cited for the very limited purpose of allegedly disclosing a surgical apparatus comprising a flexible tube (8), a cup-shaped suction device (1-3 collectively) and a tissue electrode 30 (tissue contacting side of 30) on the suction device distal surface. The electrode 30 taught by Lundback is a diagnostic or therapeutic device configured for being attached to a skin surface. Lundback does not teach or suggest a flexible suction device having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue as recited in claims 7, 28, and 43.

Ostroff is cited for the very limited purpose of allegedly disclosing electrodes with sensing and pacing capabilities. Ostroff does not teach or suggest a suction device at all.

Thus, none of the cited references teach or suggest a flexible suction device "having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue," as required by independent claims 7, 28 and 43. Even if the references could somehow be construed as teaching such a suction device (which Applicant does not concede), it would not have been obvious to modify Samson's suction cup 10 to have a size for being secured to myocardial tissue. In particular, if Samson's suction cup 10 was small enough to be secured to myocardial tissue, it would be too small for housing an electrode for obtaining a signal at the skin surface. Therefore, modifying Samson's device so that the suction cup 10 is sized for being secured to myocardial tissue would destroy the principle of operation of Samson's device, which is to obtain a signal at the skin surface through an electrode 16 disposed within the suction cup 10 that is secured to the patient's skin surface.

The surgical apparatuses recited in independent claims 7, 28, and 43 further include a metallic or metal-based tissue stimulation element (or tissue stimulation means, as in claim 43) configured to emit stimulation energy. In contrast, Samson teaches an electrode 16 for making contact with fetal skin for the purpose of monitoring characteristics of the fetus. Samson does not teach or suggest that the electrode 16 is configured to emit stimulation energy.

While Geeham, Lundback, and Ostroff may teach electrodes that are configured to emit stimulation energy, it would not have been obvious to modify the device taught by Samson to include such stimulation electrodes. In particular, it would be undesirable for the electrode in Samson's device to be configured for emitting stimulation energy, because stimulation energy would cause damage to the fetus that the electrode is attached to. Despite this, the Office Action alleges that it would have been obvious to modify the invention of Samson to provide the electrodes with both stimulation and sensing capability. However, an electrode with both stimulation and sensing capability would cause damage to a fetus, and thus, would not be attached to the scalp of the fetus in the manner described by Samson. Thus, the proposed modification would render Samson's device unsatisfactory for its intended purpose of monitoring fetal characteristics through the scalp of the fetus. As such, there is no suggestion or motivation to make the proposed modification.

Given these collective substantial deficiencies, no proper combination of the cited references discloses each element of each of independent claims 7, 28 and 43. Accordingly, the rejection cannot stand on this basis alone since the four references do not disclose each limitation of each independent claim.

Moreover, it would not be obvious to modify Samson based on the disclosure of Geeham since such general allegations in the Office Action fail to address the fact that the claims are directed to a device that is attachable to myocardial tissue by suction and is configured for emitting stimulation energy to cardiac tissue, whereas Samson is directed to a non-invasive sensing device that is applied to the head of a fetus, and Geeham is directed to an unrelated purpose of assisting with CPR by use of a device applied to a chest of a patient. Not only are these devices structured in different ways, have different sizes, and are used for different purposes, the electrodes described by Geeham apply energy of such a high magnitude to be used for defibrillation, in stark contrast to substantially lower energy levels used with the device of Samson.

Additionally, given the well known manner in which the CPR assist device is intended and designed to be utilized, the device described by Geeham is not designed for securing the suction cup member 20 to myocardial tissue. Instead, as is well known to a person skilled in the art, the assist device described by Geeham is configured for use on an outer surface of a patient's chest, not on the surface of the patient's heart. Geeham (Fig. 1) (illustrating application of device to outer chest surface). In this regard, Geeham describes a system that is used for a very different purpose and in very different ways.

The Office Action has not established, understandably so, that such a device would be utilized by opening a chest cavity and then applying the suction cup member 20 to myocardial tissue. Moreover, it is reasonable to assume that actually applying the suction cup device 20 to myocardial tissue and utilizing the CPR assist device as described by Geeham (by an aid giver pushing down and expanding upon the heart) may result in severe injury and/or death, not only from the compressions, but also from opening the patient's chest.

In view of the very different structures, functions and capabilities of the cited components of the four cited references, Applicant respectfully submits that the alleged combination of piecemeal components of these very different structures and methods described thereby do not involve combining or substituting elements according to known methods to

achieve predictable results or designs (particularly in view of the substantial and determinative deficiencies of Samson), and that in view of these substantial differences, it would not be obvious to try to the alleged combinations. Further, various references teach away from aspects of independent claims 7, 28 and 43. Accordingly it is respectfully submitted that these claims are patentable over the four cited references.

Dependent claims 10, 11, 30, 40, 46, 47 and 54-59 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed patentable over these references.

Accordingly, Applicants respectfully request that the rejection of claims 7, 10, 11, 28, 30, 40, 43, 46, 47 and 54-49 under 35 U.S.C. §103(a) be withdrawn.

II. Claims 34 and 35 Are Patentable Over Samson, Geeham Lundback and Colliou

Claims 34 and 35 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Samson in view of Geeham, Lundback, and Ostroff, and further in view of Colliou. Colliou is cited for the very limited purpose of allegedly disclosing certain stimulation pulses, but Colliou does not cure the substantial and determinative deficiencies discussed above.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests allowance of the application in view of the forgoing remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

VISTA IP LAW GROUP LLP

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By: /Jamie L. Brophy/
Jamie L. Brophy
Reg. No. 56,002

Customer Number **23410** PATENT TRADEMARK OFFICE

VISTA IP LAW GROUP LLP
2040 Main Street, Suite 710
Irvine, CA 92614
Phone (949) 724-1849
Fax (949) 625-8955